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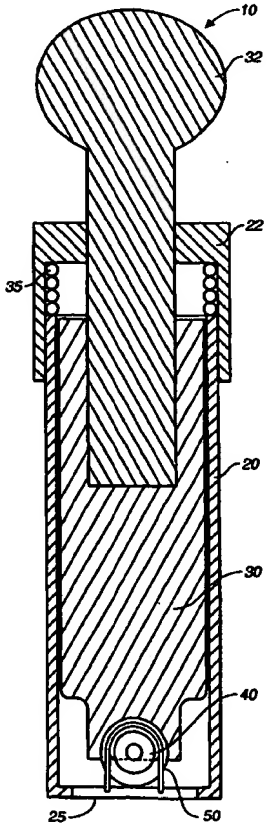
(54) Title: MINIMALLY INVASIVE ANNULOPLASTY PROCEDURE AND APPARATUS



(57) Abstract: Clips (50) of a self-closing type are used in annuloplasty procedures. Each clip (50) is generally U-shaped with two end points separated from each other when it is constrained to be in an open configuration, but tends to coil up to assume its naturally closed configuration if the constraint is removed. A plurality of such clips (50) in open configurations penetrate the tissue around the annulus circumferentially and then the constraints keeping them in the open configuration is removed such that they pull the tissue together between their two end points and this tends to reduce the diameter of the annulus. A clip delivery device (10) may be used with a plurality of such clips (50) loaded to a clip-holder (40) serving to keep them in open configurations. A pusher (30) pushes the loaded clips (50) out of the device (10) one at a time.

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MINIMALLY INVASIVE ANNULOPLASTY PROCEDURE AND APPARATUS

Background of the Invention

This invention relates to methods and apparatus for annuloplasty repair and replacement.

Valve repair and valve replacement are currently done in surgical procedures as described, for example, in "Mitral Valve Repair: Ischemic" by W. Randolph Chitwood, Jr. (Mastery of Cardiothorcic Surgery, Lippincott-Raven Publishers (1998) 309-321) and "Mitral Valve Replacement" by Kwok L. Yun and D. Craig Miller (ibid. (1998) 329-341). Cumbersome suture management, knot tying, pain and long recovery time are inherent to such surgical procedures. It now goes without saying that quickly operable methods and apparatus are desirable for allowing surgeons to perform procedures with less pain and disability than known surgical procedures. Tissue-connector apparatus and methods easily usable in such surgical procedures have recently been disclosed in U.S. patent applications Serial Nos. 09/089,884 and 09/090,305 both filed June 3, 1998 and Serial Nos. 09/259,705 and 09/260,623 both filed March 1, 2000 and International Application Nos. PCT/US99/12563 and PCT/US99/12566 both filed June 3, 1999 and published on December 9, 1999 under International Publication Nos. WO 99/62409 and WO 99/62406.

Applicant's invention generally simplifies operable annuloplasty methods and apparatus for valve repair and replacement and reduces or eliminates the need for involving cumbersome suture management and suture knotting. According to one aspect of the present invention, there is provided such methods and apparatus using the tissue-connector

apparatus disclosed in the aforementioned U.S. and international patent applications.

Summary of the Invention

Methods and apparatus embodying this invention with which known annuloplasty metnods and valve surgery simplified and and with which other advantages may be achieved are characterized as causing clips of a self-closing type to penetrate the tissue around the annulus (e.g., annulus of a mitral valve). Such a clip is typically U-shaped, having two end points, when it is constrained to be in an open configuration but is made of a wire of a shape memory material such that it tends to coil up to assume its naturally closed configuration. Thus, if a plurality of such clips in open configurations penetrate the tissue around the annulus circumferentially and then the constraint keeping them in the open configuration is removed, they pull the tissue together between their two end points, and this tends to reduce the diameter of the annulus.

Such clips may be deployed each in the form of a clip assembly, having one of its end points connected to a tissue-piecing needle through a flexible member such as a suture and a release mechanism by which the clip can be easily released. The clip is then caused to penetrate the tissue at two circumferentially separated positions one after the other. Alternatively, a clip delivery device may be used with a plurality of clips loaded to a clip-holder serving to keep these clips in their open configurations. A pusher is provided for pushing a specified number of such clips out of the device at a time. Clip assemblies of this invention can be effectively used in ring annuloplasty and valve replacement procedures by placing clips circumferentially around a ring or a mitral prosthesis sewing cuff. Cumbersome problems associated with suture management and suture knotting can be thereby obviated.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and form a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention. In the drawings:

Fig. 1 is an external view of a single-arm clip assembly which may be used in an annuloplasty method embodying this invention;

Figs. 1A and 1B show a release mechanism for the clip of Fig. 1;

Fig. 1C shows a similar release mechanism arranged for the other end of a double arm clip such as shown in Fig. 9;

Fig. 2 is a schematic view of the clip assembly of Fig. 1 being used in an annuloplasty procedure;

Fig. 3 is a sectional front view of a clip delivery device embodying this invention;

Fig. 4 is a sectional side view of the clip delivery device of Fig. 3;

Fig. 5 is a side view of the cartridges shown in Figs. 3 and 4;

Fig. 6 is an axial view of the cartridge shown in Figs. 3, 4 and 5;

Fig. 7A is a sketch of the clip assembly of Fig. 1 being used in a ring annuloplasty procedure and Fig. 7B is a sketch of the ring which has been attached to an annulus by a procedure embodying this invention;

Fig. 8A is a sketch of the clip assembly of Fig. 1 being used in a valve replacement procedure and Fig. 8B is a sketch of the mitral prosthesis sewing cuff which has been inserted in a procedure embodying this invention.

Fig. 9 is an external view of a double-arm clip assembly which may be used in an annuloplasty method embodying this invention; and

Fig. 10 is a sketch of the clip assembly of Fig. 9 being used in a ring annuloplasty procedure.

Throughout herein, like components are indicated by the same numerals even where they are components of different assemblies and may not be repetitiously described for explanation.

Detailed Description of the Invention

This invention relates to methods and apparatus for annuloplasty repair and replacement, characterized as using staples, or surgical clips (hereinafter referred to as "clips") of the so-called self-closing kind. A clip of a self-closing type may be broadly characterized as having two end points which tend to come closer together either by elasticity or so-called pseudoelasticity. Such a clip may be made by heat-treating a NiTi wire to a certain temperature and time to have a desired undeformed shape. Examples of such clips, including methods of making them as well as materials which may be used, were disclosed in aforementioned U.S. patent applications Serial Nos. 09/089,884, 09/090,305, 09/259,705 and 09/260,623, and International Application Nos. PCT/US99/12563 and PCT/US99/12566 both filed June 3, 1999 and published on December 9, 1999 under International Publication Nos. WO 99/62409 and WO 99/62406, comprising a wire of a shape memory alloy. For the purpose of the present invention, the minimum conditions such clips should satisfy include that they each have two end points, have a naturally closed configuration, can be forced to assume an open configuration but will tend to return to the naturally closed configuration by reducing the separation between these two end points if forced to assume the open configuration. The clips disclosed in aforementioned U.S. patent applications Serial Nos. 09/089,884, 09/090,305, 09/259,705 and 09/260,623 and International Application Nos. PCT/US99/12563 and PCT/US99/12566 (all herein incorporated by reference), comprising a

deformable wire made of a shape memory alloy and assuming a U-shape when in the open configuration, satisfy all these required conditions.

Such a clip may be deployed, for example, in the form of a single-arm clip assembly as generally shown in Fig. 1 at 1 (as well as in aforementioned U.S. patent applications Serial Nos. 09/089,884 and 09/090,305, and the section of International Application No. PCT/US99/12566 from page 10, line 10 through page 11, line 21, which section and accompanying Fig. 1 is hereby specifically incorporated by reference herein) with a tissue-piercing needle 3 connected through a flexible member 4 such as a suture to one of the end points of such a clip 5 which is constrained to assume a generally U-shaped open configuration, the other end point of the clip 5 being formed as a stopper 6 for anchoring the clip 5 to the tissue, as will be explained below. A release mechanism 7, such as disclosed in aforementioned U.S. patent application Serial No. 09/260,623, (or International Application No. PCT/US99/12566, which published on December 9, 1999 under International Publication Nos. WO 99/62406) is provided such that the clip 5 can be easily released, say, by pressing thereon by a surgical instrument. For the sake of particular example, the release mechanism description in International Application No. PCT/US99/12566 from page 25, line12 through page 27, line 30 ending with the text "mechanism 23c" (but without the text "such as needle 17 as shown in Fig. 1" on line 27 of page 27) and the referenced figures are hereby incorporated by reference herein. A summary of such a release mechanism is provided below with reference to Figs. 1A-C.

Referring to Figs. 1A and B a release mechanism 7' generally comprises a plurality of substantially rigid strands, cables or wires 106, which may be metallic, and which are arranged substantially parallel to one another and circularly about a longitudinal axis. The hidden end

portions of the strands are coupled to tapered section "T", which is coupled to a piercing member or needle through a flexible member 4. The strands may be coupled to rod 162, which is fixed to the tapered element. End portions of the strands include notches, which form a chamber 108 for releasably receiving enlarged portion "E" of the clip (or fastener wire "W." According to the cited PCT application, the notches preferably are placed about 0.015 from the free ends of the strands, but this distance can be varied depending upon the desired compression on the fastener or clip spring. A shrink wrap layer, preferably a shrink tubing 110 as set forth in the cited PCT application is provided around at least the free end portions of the strands and the shrink wrap or tubing heated to compress against the strands and hold them in place against the enlarged wire portion to effectively hold the enlarged portion captive until the shrink wrap is squeezed, the strands displaced and the enlarged portion released. Referring to Fig. 1C, the release mechanism may also be used to releaseably couple the other end of the fastener to another flexible member and needle as shown in Fig. 9. In this arrangement, an annular member or stopper 115 is secured to the other end of the fastener or wire to prevent the enlarged portion of the wire at this end from passing through the compression spring upon release of from the release mechanism.

Fig. 2 illustrates a method of annuloplasty embodying this invention by using the single-arm clip assembly 1 of Fig. 1. The surgeon will guide the needle 3 to the surgical site, cause it to penetrate and pass through the tissue of the annulus sequentially at two positions one after the other which are circumferentially separated with respect to the annulus, and pull the flexible member 4 such that the clip 5 will have its two end points penetrate the tissue at these two positions. The stopper 6 serves to secure the clip 5 at this position. After the release mechanism

7 is pressed and the needle 3 is released from the clip 5, the clip 5 tends to return to its naturally closed configuration, tending to bring the two end points closer towards each other, thereby pinching the portion of the tissue therebetween. After one clip 5 is thus placed in the annulus, the same procedure is repeated with a plurality of other clips 5. These clips 5 are placed circumferentially, either serially or overlappingly, as shown in Fig. 2. Since the placed clips 5 tend to return to their naturally closed configurations by reducing the gap between their end points, the net effect is to reduce the circumference of the annulus.

Figs. 3 and 4 show a clip delivery device 10 embodying this invention for carrying out an annuloplasty procedure in an alternative way. Broadly explained, the device 10 is comprised of an outer tube 20 with a hollow cylindrical interior and an elongated slit 25 at the bottom, affixed to a cap 22, a pusher 30 provided with a knob 32 and adapted to be pushed longitudinally inside the outer tube 20 for pushing one clip at a time, and a pair of cartridges 40 for mounting clips 50 thereon.

Each cartridge 40 is generally of a cylindrical shape attached to a fixture 41, as shown in Figs. 5 and 6, with a quasi-circular cross-sectional shape and serves to have a plurality of clips 50 mounted thereon one next to another in a generally U-shaped open configuration with their end points pointing uniformly downward. The two cartridges 40 are positioned coaxially in a face-to-face relationship, extending perpendicularly to the slit 25 at the bottom of the outer tube 20, leaving therebetween a narrow gap 45 barely wide enough for one of the clips 50 to pass through vertically. Each carriage 40 is provided with a spring 42 such that the clips 50 mounted thereon are biased towards the gap 45. Each cartridge 40 has chamfered edge portion 47 adjacent the gap 45.

To assemble the device 10, the cartridges 40, fully loaded with the clips 50, are positioned inside the outer tube 20, as shown in Figs. 3 and

4. The pusher 30 is inserted thereafter into the outer tube 20, and a spring 35 and the cap 22 are assembled onto the outer tube 20. Finally, the knob 32 is screwed into the pusher 30 to complete the clip delivery device 10.

In an annuloplasty procedure, the device 10, fully loaded with clips 50, is guided to a desired surgical site and oriented appropriately. As the knob 32 is pressed against the biasing force of the spring 35, the pusher 30 moves down and pushes one of the clips 50 which may originally have been on either of the cartridges 40 but has been pushed by the springs 42 to the position of the gap 45. Since the gap 45 is exactly above the slit 25 at the bottom of the outer tube 20, the clip 50 at the gap 45 is pushed out through the slit 25 to be inserted into the patient's tissue, both end points penetrating the tissue simultaneously at two positions that are separated circumferentially with respect to the annulus, as shown in Fig. 2, in the same way in which a staple is pushed out of a stapler of an ordinary kind.

Once thus deployed, the clip 50 tends to return to its naturally closed configuration, by reducing the distance between its two end points. Since the tissue is less firm than the cartridges 40, the portion of the tissue between the two end points of the clip 50 plicates to a certain extent, allowing the two end points of the clip 50 to come somewhat closer than when the clip 50 was kept on the cartridge 40. After a plurality of such clips 50 are thus implanted circumferentially as shown in Fig. 2, the net effect is to reduce the circumference of the annulus.

In the description of the device 10 above, the gap 45 was described as being barely wide enough to one of the clips 50 to be pushed down at a time, but this is not intended to limit the scope of the invention. There may be circumstances under which it is preferable to deploy a plurality of clips 50 at once. For situations like this, the gap 45

may be accordingly increased. In practice, it may be found advantageous to be provided with more than one such devices 10 each having a gap 45 of a different width such that different specified numbers of clips can be deployed from the provided devices 10.

Clip assemblies as shown at 1 in Fig. 1 may be used in a ring annuloplasty as shown, for example, in Figs. 7A and 7B by using an annuloplasty ring 60 of a known kind. Although an open ring 60 is shown for illustration, a ring of a closed shape may be used. Fig. 7A shows the clip assembly 1 being used, with the needle 3 operated to penetrate the ring 60 at one position 60a, then into the tissue at one position 90a and out therefrom at another position 90b of the annulus and then again through the ring 60 at another position 60b. These positions 60a, 90a, 90b and 60b are selected such that the distance between the two positions 60a and 60b of penetration through the ring 60 is smaller than the distance between the position 90a of entry into the tissue by the needle 3 and the position 90b at which the needle 3 is pulled out of the tissue. After the stitching operation in an ordinary manner by the needle 3 described above is completed and the situation depicted in Fig. 7A is reached, the flexible member 4 is pulled until the clip 5 passes partially through the ring 60, its end point connected to the flexible member 4 having completely passed through the ring 60 twice and the other end point being stopped by the stopper 6 before penetrating the ring 60. This has the effect of contracting the portion of the tissue between the two positions 90a and 90b to the smaller distance between the two points of penetration 60a and 60b through the ring 60 by the needle 3 than the original separation of these two positions 90a and 90b of the tissue before the stitching is carried out. The flexible member 4 is thereafter released from the clip 5 by pressing the release mechanism 7, as described above. The clip 5, deployed while it was in an open

configuration, has now only the ring 60 and the portion of the tissue between its two end points to prevent it from completely returning to its naturally closed configuration but still tends to reduce the distance separating the two end points. This internal force of the clip 5 tends to keep the ring 60 firmly attached to the tissue, thereby allowing the ring 60 to perform its intended function of keeping the annulus in its intended size.

Fig. 7B shows the ring 60 fastened around the annulus after a plurality of clips 5 have thus been deployed to keep the ring 60 at the surgical site. The clips 5 may be positioned to be circumferentially overlapping or separated. The two modes of arrangement may also be mixed.

The clip assembly 1 shown in Fig. 1 may be used also in a valve replacement procedure wherein mitral valve portions are removed and a mitral prosthesis sewing cuff is inserted.

The method of valve replacement according to this invention is again characterized as using clips of a self-closing kind as described above. Fig. 8A shows the clip assembly 1 being used, with the needle 3 operated to penetrate a mitral prosthesis sewing cuff 70 at one position, then into the tissue at one position where the prosthesis sewing cuff 70 is to be placed and out therefrom at another position of the tissue and then again through the prosthesis sewing cuff 70. After the situation depicted in Fig. 8A is reached, the flexible member 4 is pulled until the clip 5 passes partially through the prosthesis sewing cuff 70, its end point connected to the flexible member 4 completely passing through the prosthesis sewing cuff 70 twice and the other end point being stopped before penetrating the prosthesis sewing cuff 70 by the stopper 6. The flexible member 4 is thereafter released from the clip 5 by pressing the release mechanism 7, as described above. The clip 5, deployed while it

was in an open configuration, has now only the prosthesis sewing cuff 70 and the portion of the tissue between its two end points to prevent it from returning to its naturally closed configuration but still tends to reduce the distance separating the two end points. This force of the clip 5 tends to keep the prosthesis sewing cuff 70 attached to the tissue.

Although the invention was described above with reference to only a limited number of embodiments, they are not intended to limit the scope of the invention. Many modifications and variations are possible within the scope of the invention. For example, a clip of the kind described above may be deployed in the form of a double-arm clip assembly as generally shown in Fig. 9 at 101, as well as in aforementioned U.S. patent applications Serial Nos. 09/259,705 and 09/260,623, having a tissue-piercing needle 3 connected through a flexible member 4 such as a suture to each of the end points of a clip 5, maintained in its generally U-shaped open configuration. A release mechanism 7 is provided at each end point of the clip 5 such that the clip 5 can be easily released from the flexible member 4. A further description of a suitable double-arm clip assembly is provided in International Application No. PCT/US99/12566, the section and figure described from page 24, line 8 through line 14 and ending with the term "configuration" being specifically incorporated by reference herein.

Fig. 10 shows the double-arm clip assembly 101 being used in a ring annuloplasty process. The pair of needles 3 are each caused to penetrate the tissue and be pulled out and then penetrate through a ring 60 such that the distance between the two positions at which the needles 3 are caused to penetrate and come out of the tissue is greater than the distance between the two positions on the ring 60 where the needles 3 pass through the ring 60, as explained above with reference to Fig. 7A. After the stitching with the needles 3 as described above is completed

and the situation depicted in Fig. 10 is reached, the flexible member 4 is pulled until the both end points of the clip 5 in its open configuration pass through the tissue and the ring 60. The flexible members 4 are then released from the clip 5 by pressing the release mechanisms 7, and the tendency of the clip 5 to coil up and return to its closed configuration serves to keep the ring 60 firmly attached to the tissue, as explained above with reference to the single-arm clip assembly 1.

What is claimed is:

1. An annuloplasty method comprising:

providing clips each having two end points which are separated from each other when the clip is in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration; and

placing said clips around an annulus by causing both of the two end points of each of said clips in said open configuration to penetrate tissue of said annulus at two circumferentially separated positions, whereby said clips reduce diameter of said annulus.

2. The method of claim 1 wherein one of said two end points of each of said clips is connected through a flexible member to a tissue-piercing needle and said clips are placed around the annulus each by causing the associated one of the needles connected thereto to penetrate the tissue at one position and to come out thereof at another position which is circumferentially separated from said one position.

3. The method of claim 1 wherein said clips are loaded in a clip delivery device, a specified number of said clips being pushed out of said delivery device at a time, each of said clips having both end points thereof to penetrate said tissue simultaneously.

4. The method of claim 1 wherein said clips are each generally U-shaped when in said open configuration, comprising a wire of a shape memory material.

5. A clip delivery device for annuloplasty, said device comprising:

a plurality of clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration;

a clip-holder supporting said clips in said open configuration; and

a pusher for pushing a specified number of said clips at a time by causing said two end points thereof to leave said device simultaneously together.

6. The device of claim 5 further comprising an outer tube extending in a longitudinal direction and having an elongated slit at one end, said pusher being elongated and adapted to slide in said longitudinal direction inside said outer tube and to thereby push said specified number of clips at a time through said slit.

7. The device of claim 6 wherein said clip-holder comprises:

a pair of cylindrical cartridges coaxially disposed with a gap therebetween and adjacent said slit, said clips being mounted in said open configuration to said cartridges, said gap being wide enough to allow only said specified number of said clips to pass therethrough at a time to be pushed out of said device together; and

a pair of springs for pushing said clips over and along said cartridges towards said gap.

8. The device of claim 5 wherein said clips are each generally U-shaped when in said open configuration, comprising a wire of a shape memory material.

9. A mitral valve repair method comprising:

providing clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration;

placing an annuloplasty ring about an annulus; and

attaching said ring around said annulus by causing said clips to pass through said ring.

10. The repair method of claim 9 wherein said clips are attached to said ring in circumferential directions along said ring.

11. The repair method of claim 9 wherein each of said clips has a tissue-penetrating needle releasably attached through a flexible member to one of said two end points thereof and said step of attaching said ring comprises the steps of:

causing the needle associated with said each clip to penetrate and pass through said ring and tissue of said annulus; and

thereafter pulling said flexible member to position said each clip so as to hold said ring to said tissue.

12. The repair method of claim 11 wherein said needle is caused to pass through said ring at two positions separated by a shorter distance, to penetrate said tissue at one position and to come out therefrom at another position separated from said one position by a larger distance than said shorter distance.

13. The repair method of claim 9 wherein said clips are each generally U-shaped when in said open configuration, comprising a wire of a shape memory material.

14. The repair method of claim 9 wherein each of said clips has a tissue-penetrating needle releasably attached through a flexible member to each of said two end points thereof and attaching said ring comprises:

causing each of the needles of each of said clips to penetrate and come out of the annulus and to pass through said ring; and

thereafter pulling the flexible members to position said each clip so as to hold said ring to said tissue.

15. A mitral valve replacement method comprising:

providing clips each having two end points which are separated from each other when in an open configuration and tending to return to a naturally closed configuration by reducing distance between said end points when in said open configuration;

removing mitral valve portions to be replaced;

placing a prosthesis sewing cuff therefor where said valve portions have been removed;

attaching said prosthesis sewing cuff to a tissue around said removed valve portions by causing said clips to penetrate both said prosthesis sewing cuff and said tissue.

16. The replacement method of claim 15 wherein each of said clips has a tissue-penetrating needle releasably attached through a flexible member to one of said two end points thereof and attaching said prosthesis sewing cuff comprises:

causing the needle associated with said each clip to penetrate and pass through said prosthesis sewing cuff and tissue of said annulus; and

thereafter pulling said flexible member to position said each clip so as to hold said prosthesis sewing cuff to said tissue.

17. The replacement method of claim 15 wherein each of said clips has a tissue-penetrating needle releasably attached through a flexible member to each of said two end points thereof and attaching said prosthesis sewing cuff comprises:

causing the needle associated with said each clip to penetrate and pass through said prosthesis sewing cuff and tissue of said annulus; and

thereafter pulling said flexible member to position said each clip so as to hold said prosthesis sewing cuff to said tissue.

18. The replacement method of claim 15 wherein said clips are each generally U-shaped when in said open configuration, comprising a wire of a shape memory material.

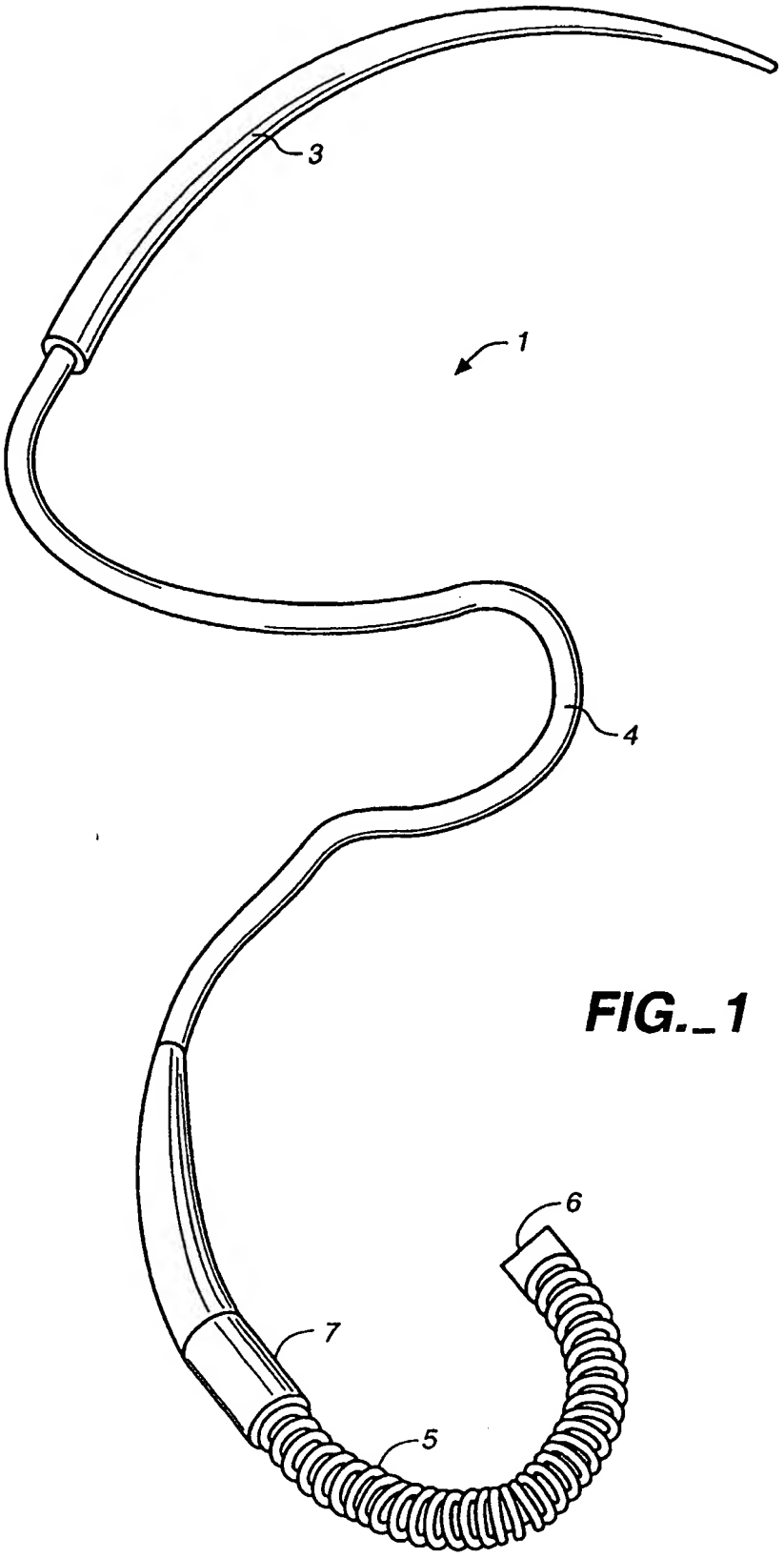

FIG._1

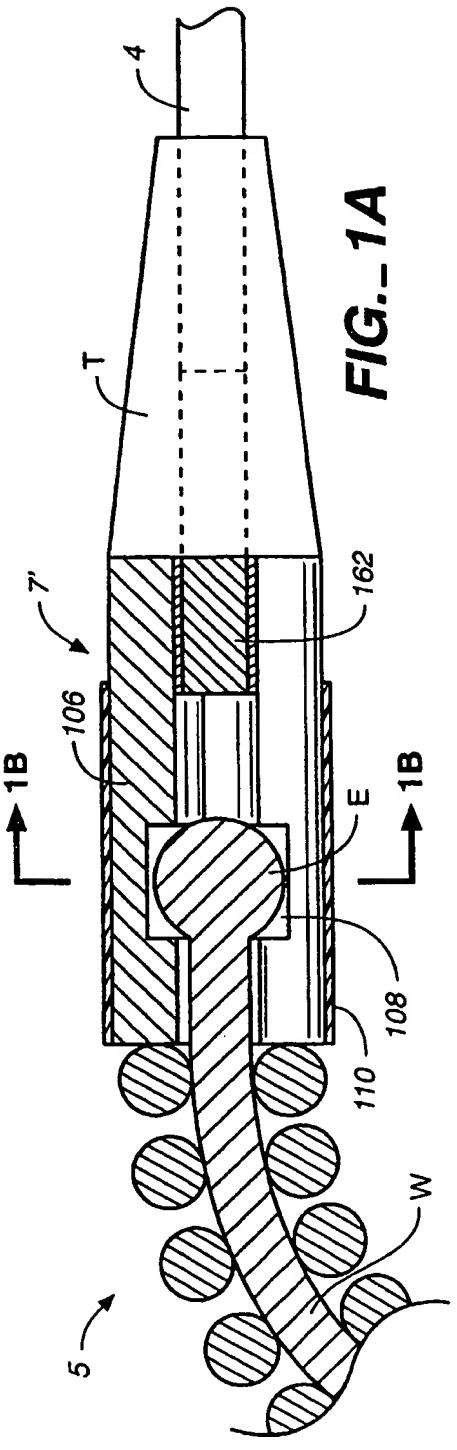

FIG._1A

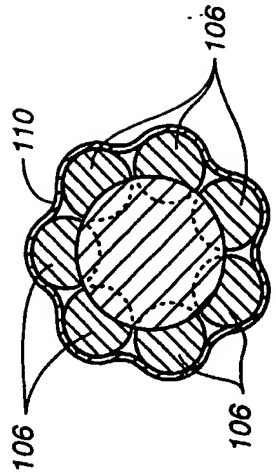

FIG._1B

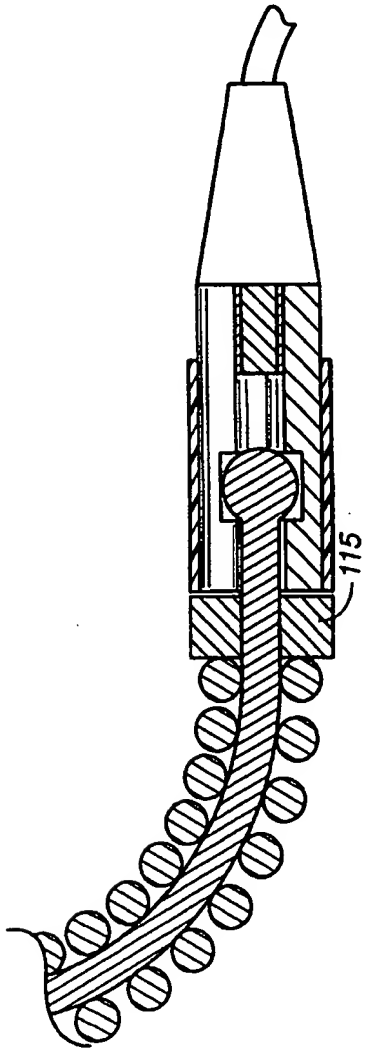

FIG._1C

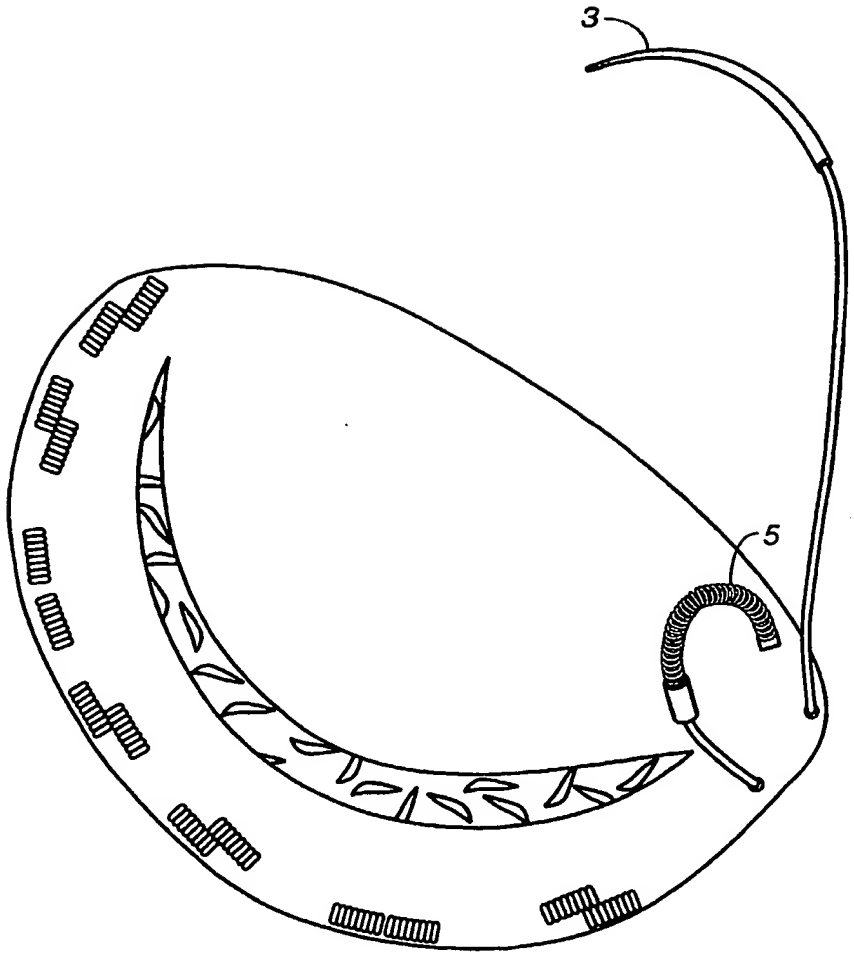

FIG._2

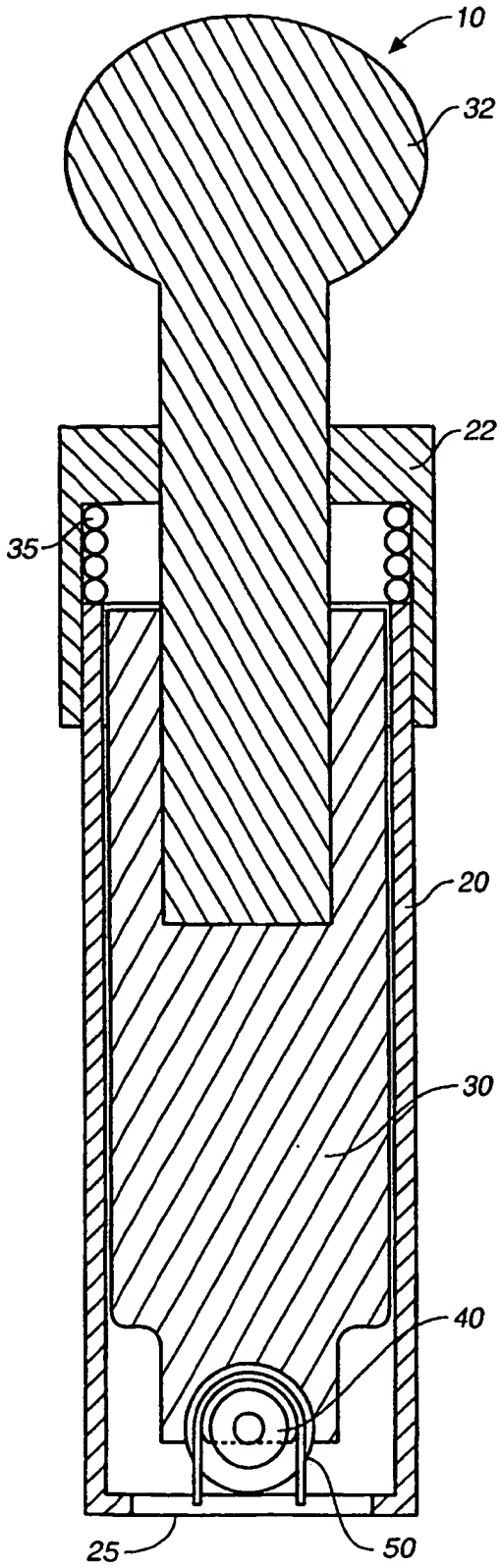

FIG. 3

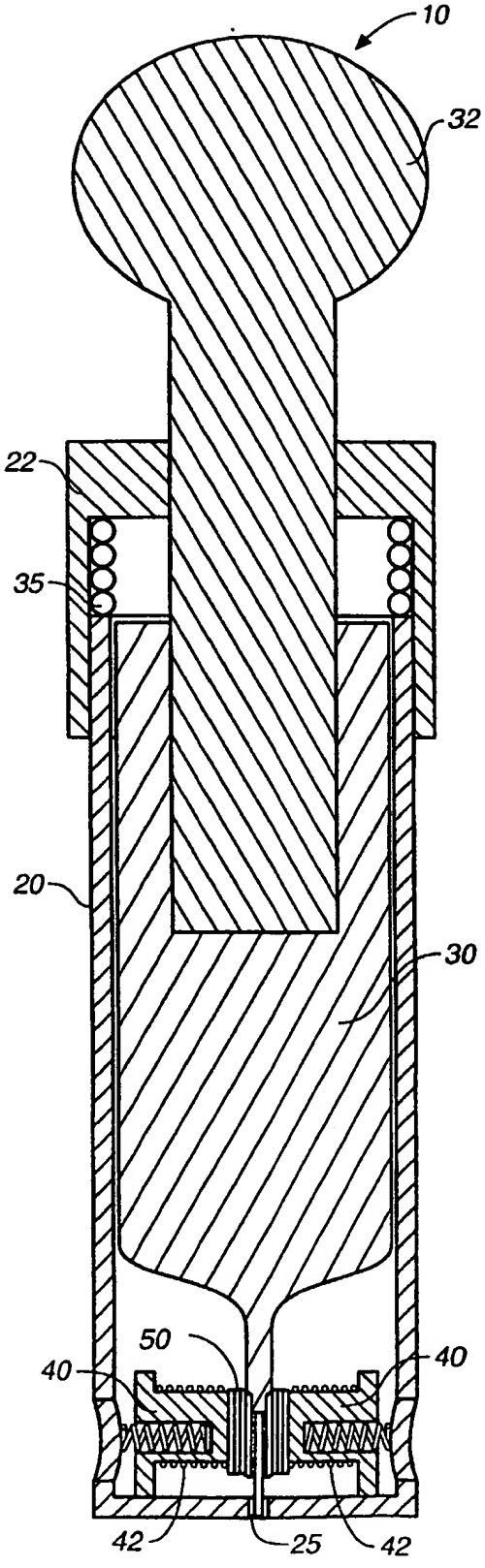

FIG._4

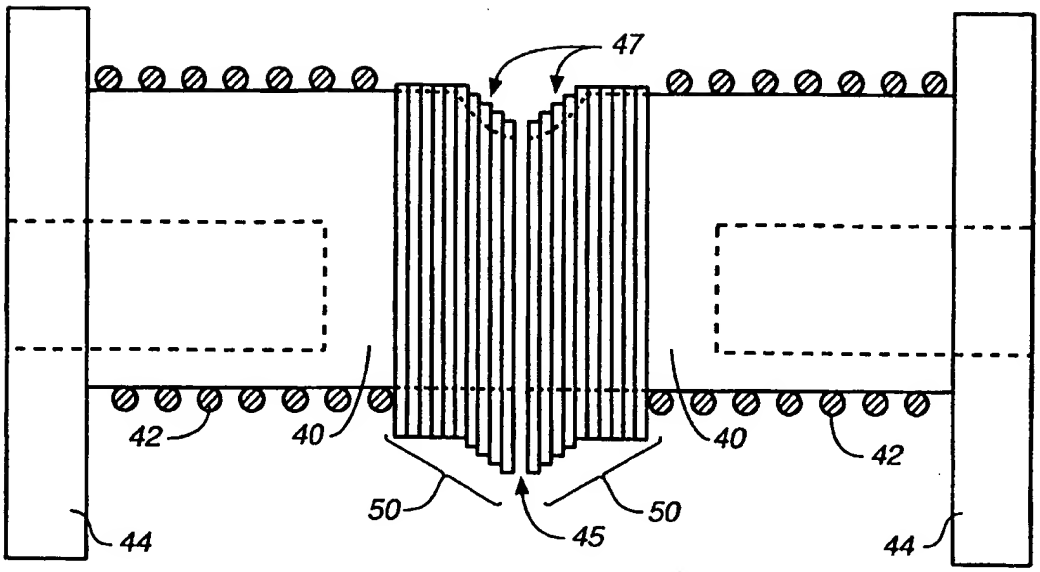

FIG._5

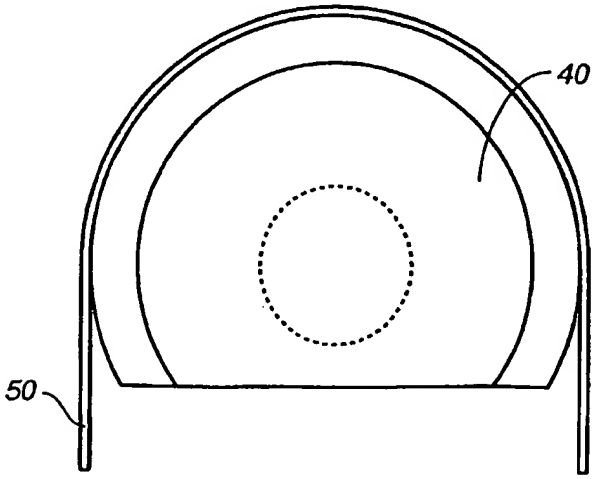

FIG._6

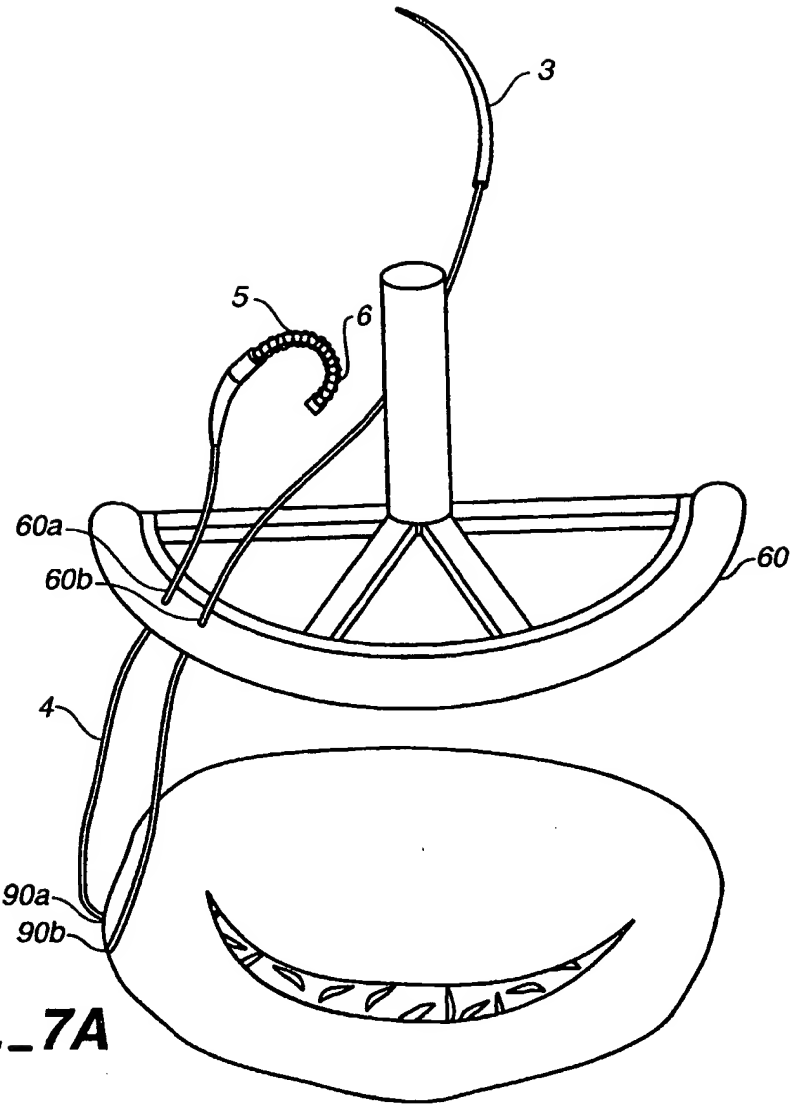

FIG._7A

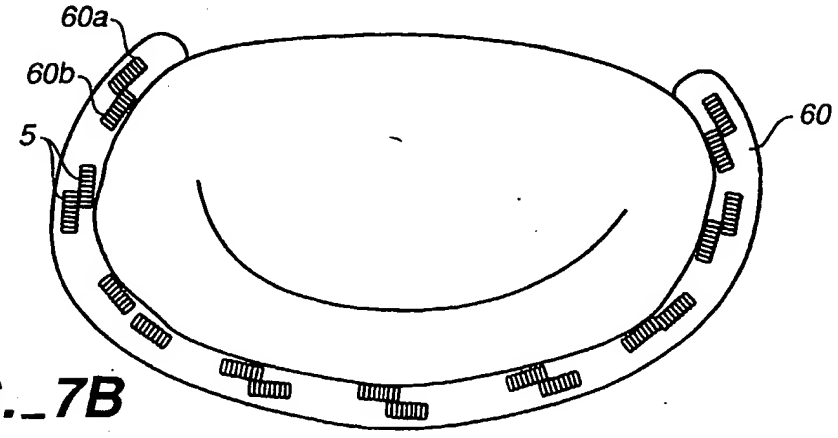

FIG._7B

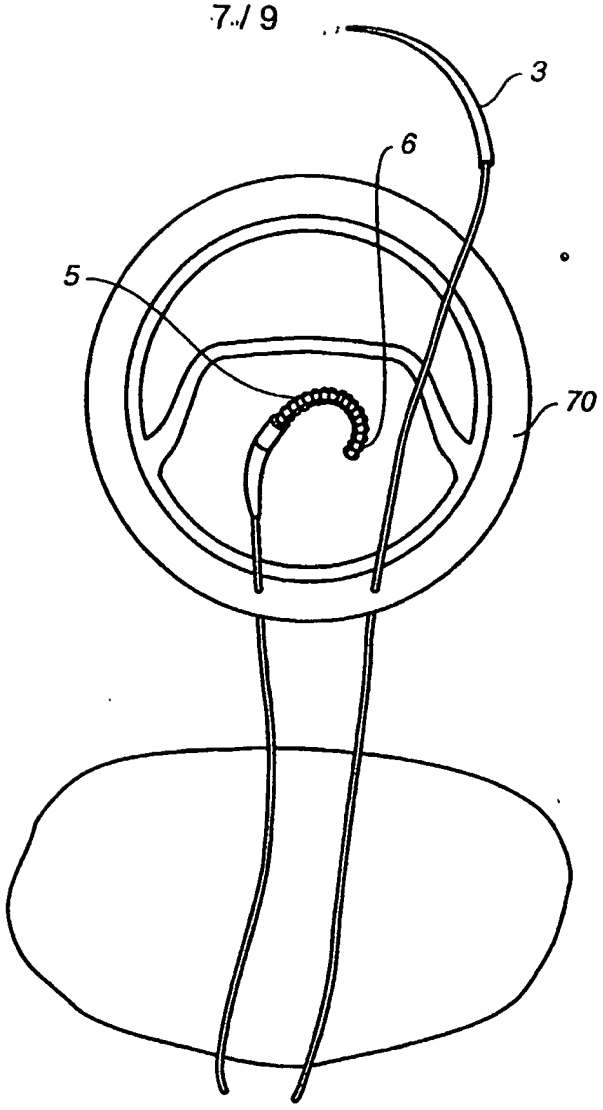

FIG._8A

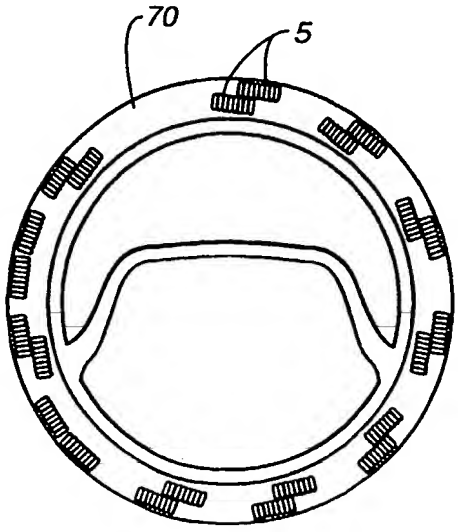

FIG._8B

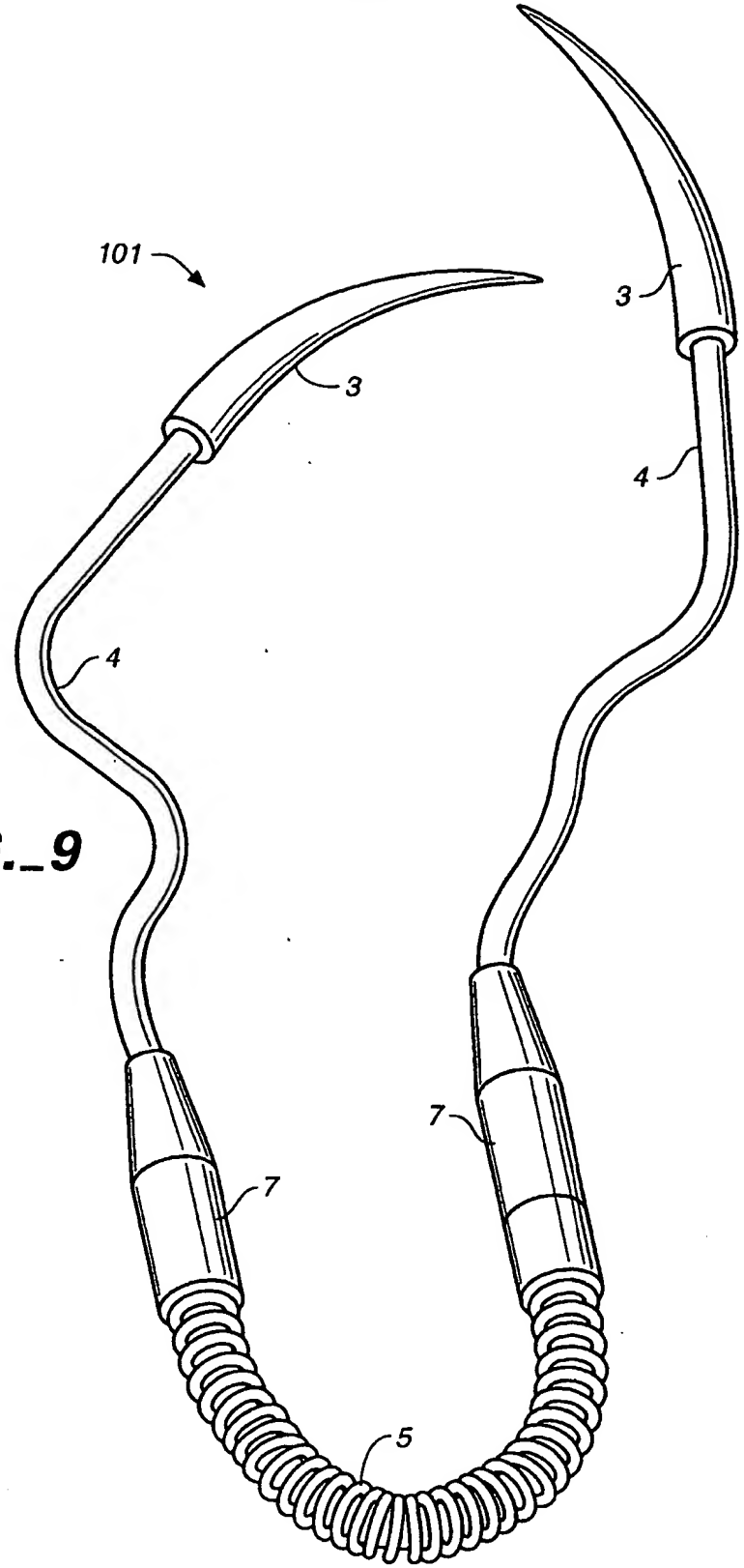

FIG._9

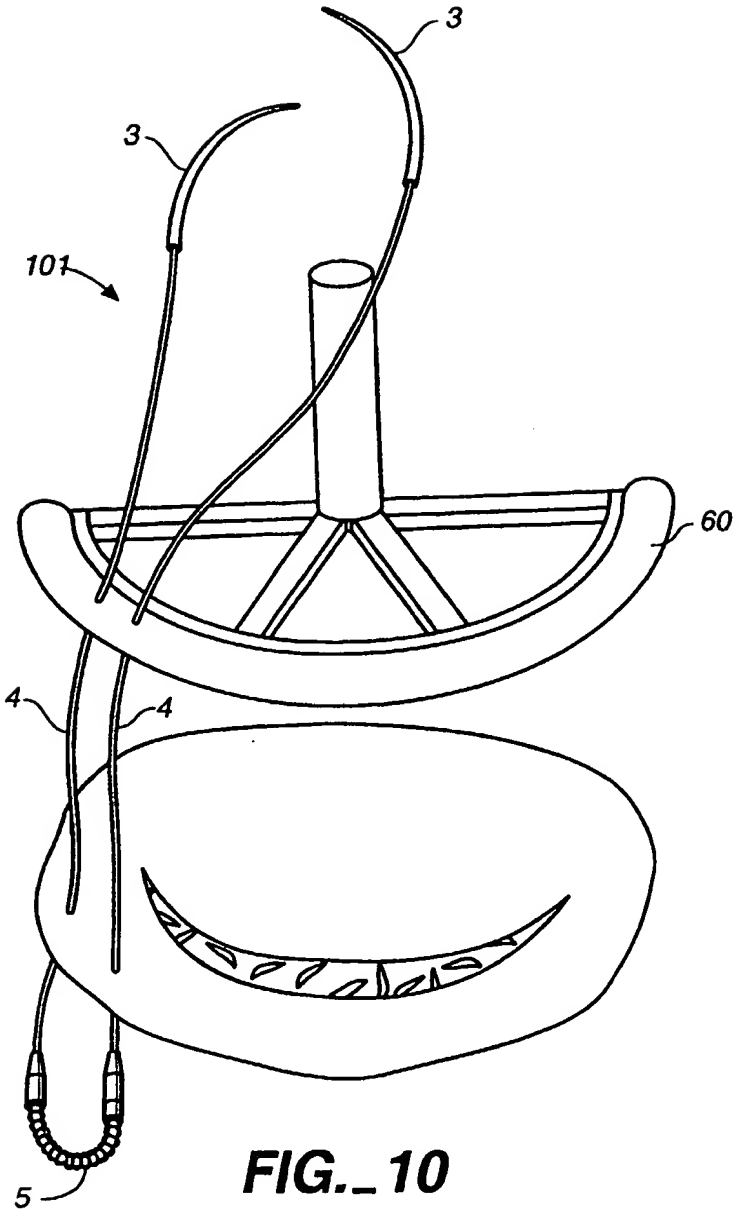

FIG._10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/42653

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/10
US CL :606/139

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 142, 143, 148, 153, 213, 216, 221; 623/2.36, 2.37, 2.38, 2.39, 2.4, 2.41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS
search terms: annuloplasty, needle, suture, valve, clip, cuff, annulus, coil, mitral, valve, heart, cartridge, valvuloplasty

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,825,009 A (WILLIAMS) 23 July 1974, see entire document.	1-18
A	US 4,396,139 A (HALL et al.) 02 August 1983, see entire document.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 25 JANUARY 2002	Date of mailing of the international search report 14 MAR 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JULIAN W. WOO Telephone No. (703) 308-0421

Form PCT/ISA/210 (second sheet) (July 1998)★